SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6861–6900

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted in whole or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(d), the article was for use by man and contained a quantity of a chemical derivative of barbituric acid, which derivative had been found to be, and by regulations designated as, habit forming, and its label failed to bear the statement "Warning—May be habit forming."; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug; and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUG FOR HUMAN USE

6861. Entoquel syrup and Entoquel with Neomycin syrup. (F.D.C. No. 46218. S. Nos. 20-908/9 R.)

QUANTITY: 25 6-oz. btls. of *Entoquel syrup* and 32 6-oz. btls. of *Entoquel with Neomycin syrup*, at Cleveland, Ohio, in possession of Grey Drug Stores, Inc.

SHIPPED: 2–6–61, from Kenilworth, N.J., by White Laboratories, Inc.

LABEL IN PART: (Btl.) "Entoquel Syrup (Thihexinol Methyl Bromide) Caution: * * * White Laboratories, Inc., Kenilworth, New Jersey. Dosage * * * Each Teaspoon (5 cc) contains * * * Thihexinol Methyl Bromide–5 mg. Alcohol –1%" and "Entoquel with Neomycin Syrup Caution: * * * White Laboratories, Inc. * * * Dosage: * * * Each teaspoon (5 cc) contains * * * Thihexinol (Entoquel)–5 mg. Neomycin (from the sulfate)–50 mg. Alcohol–0.5%."

ACCOMPANYING LABELING: Promotional form letter entitled "Dear Doctor" and leaflet entitled "Are opiates now outmoded in pediatric diarrhea?"

LIBELED: 8–1–61, N. Dist. Ohio.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the article "acts almost exclusively to inhibit gastrointestinal motor function and does not interfere with gastric secretion, digestive processes, or produce other undesirable atropine like effects when given in the recommended dosage" and that the "only side effect noted was a mild, more or less transient flushing of the skin"; will successfully treat diarrhea, which threatens pediatric patients, without side effects; and stop diarrhea rapidly, without side effects; 502(f)(1)—the labeling of the articles failed to bear adequate directions for use and it was not exempt from the requirement since the promotional material for the new drugs was not the same as, or substantially the same as, the labeling authorized by the effective new drug applications; and 505(a)—the effective new drug application did not apply to the conditions for which the articles were promoted to the medical profession, namely, for the treatment of complications of severe pediatric diarrhea-dehydration, electrolyte imbalance, weight loss, pale, ashen skin, sunken fontanel, distended abdomen, and constant crying; nonspecific digestive upsets and for nausea and vomiting.

DISPOSITION: 10–18–61. Default—destruction.

DRUG FOR VETERINARY USE

6862. Zoamix medicated feed premix. (F.D.C. No. 46851. S. Nos. 6–468 T, 7–342 T.)

QUANTITY: 63 50-lb. bags at Augusta, Maine.

SHIPPED: 10–25–61 and 11–28–61, from Newark, N.J.

LABEL IN PART: "ZOAMIX A Premix Medicated * * * For Chickens Only. Active Ingredients: Zoalene (3.5-Dinitro-O-Toluamide) 25%."

RESULTS OF INVESTIGATION: The manufacturer of the article had filed a new drug application which was effective with respect to shipments of the article made to feed manufacturers who had filed effective supplemental new drug applications covering the use of the article in finished feeds. Investigation revealed that the article had been purchased by a dealer at Augusta, Maine for use in the feeds which he manufactured but that such dealer had not filed a supplemental new drug application which was effective for such use.

LIBELED: 12–13–61, Dist. Maine.

CHARGE: 505(a)—the article was a new drug, and an application filed pursuant to law was not effective with respect to the article.

DISPOSITION: 1–3–62. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6863. Various prescription drugs. (F.D.C. No. 46109. S. Nos. 50–529/33 R, 50–535/8 R.)

QUANTITY: 6,431 tablets and capsules and 70 clips of vials, btls., and packs, at Denver, Colo., in possession of Earl Meyer Drug Co.

SHIPPED: On unknown dates, by various drug handlers.